

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Re: Application of: Benjamin OSHLACK, et al.  
Serial No.: To be Assigned  
Filed: Herewith  
Examiner: To be Assigned  
For: **CONTROLLED RELEASE OXYCODONE  
COMPOSITIONS**

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA, 22313-1450

November 12, 2003

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. §1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the references listed on the accompanying Form PTO-1449 (13 pages) for consideration by the Examiner in connection with the examination of the above-identified patent application. Pursuant to 37 C.F.R. § 1.98(d), copies of the references listed on pages 1-13 of the Form PTO-1449 are not enclosed because these references have already been made of record in the parent case, U.S. Patent Application Serial No. 10/163,484.

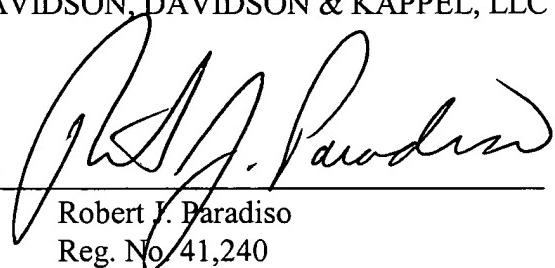
The present Information Disclosure Statement is filed under 37 C.F.R. §1.97(b), before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. However, if it is determined that any fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

It is respectfully requested that the reference cited on the accompanying Form PTO-1449  
be considered and made of record.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By



A handwritten signature in black ink, appearing to read "R.J. Paradiso". The signature is fluid and cursive, with a large, stylized 'P' at the beginning.

Robert J. Paradiso  
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940

<b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)				ATTY DOCKET NO.	APPLICATION NO	
				200.93311 CON8		To be Assigned
				APPLICANT	Benjamin OSHLACK, et al.	
				FILING DATE	GROUP	
				Herewith		

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	2,921,883	1/19/60	Reese et al.	167	82	
	A02	3,082,154	3/19/63	Allan	167	82	
	A03	3,492,397	1/27/70	Peters et al.	424	20	
	A04	3,773,920	11/20/73	Nakamoto et al.	424	19	
	A05	3,922,339	11/25/75	Shear	424	22	
	A06	3,965,256	6/22/76	Leslie	424	22	
	A07	4,443,428	4/17/84	Oshlack et al.	424	22	
	A08	4,708,874	11/24/87	De Haan et al.	424	470	
	A09	4,722,815	2/2/88	Shibanai	264	117	
	A10	4,828,836	5/9/89	Elger et al.	424	419	
	A11	4,834,984	5/30/89	Goldie et al.	424	488	
	A12	4,834,985	5/30/89	Elger et al.	424	488	
	A13	4,844,909	7/4/89	Goldie et al.	424	480	
	A14	4,861,598	8/29/89	Oshlack	424	468	
	A15	4,970,075	11/13/90	Oshlack	424	451	
	A16	4,990,341	2/5/91	Goldie et al.	424	484	
	A17	5,215,758	6/1/93	Krishnamurthy	424	488	
	A18	5,266,331	11/30/93	Oshlack et al.	424	468	
	A19	5,273,760	12/28/93	Oshlack et al.	424	480	
	A20	5,286,493	2/15/94	Oshlack et al.	424	468	
	A21	5,356,467	10/18/94	Oshlack et al.	106	153	
	A22	5,508,042	4/16/96	Oshlack et al.	424	468	
	A23	5,508,403	4/16/96	Akiyama et al.	544	337	
	A24	5,549,912	8/27/96	Oshlack et al.	424	468	
	A25	5,656,295	8/12/97	Oshlack et al.	424	468	
	A26	5,811,126	9/22/98	Krishnamurthy	424	498	
	A27	5,958,452	9/28/99	Oshlack et al.	424	457	
	A28	5,968,551	10/19/99	Oshlack et al.	424	456	
	A29	6,103,261	8/15/00	Chasin et al.	424	459	
	A30	6,261,599 B1	7/17/01	Oshlack et al.	424	457	
	A31	6,294,195 B1	9/25/01	Oshlack et al.	424	457	
	A32	6,419,960 B1	7/16/02	Krishnamurthy et al.	424	490	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES <input type="checkbox"/> NO <input type="checkbox"/>
	A33	635,283	6/23/82	Canada	167	167	<input type="checkbox"/> <input type="checkbox"/>
	A34	02/100382 A2	12/19/02	PCT	A61K	9/26	<input type="checkbox"/> <input type="checkbox"/>
	A35	03/004030 A1	1/16/03	PCT	A61K	31/485	<input type="checkbox"/> <input type="checkbox"/>
							<input type="checkbox"/> <input type="checkbox"/>
							<input type="checkbox"/> <input type="checkbox"/>
							<input type="checkbox"/> <input type="checkbox"/>
							<input type="checkbox"/> <input type="checkbox"/>

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	A36	Agabeyoglu, I. and A. O. Ecz Fak, <i>Studies on Sustained Release II: In Vivo Performance of the Inert Matrix Sulfamethizole Tablet, Employing Polymethylmethacrylate</i> , 12 (3) DRUG DEVELOPMENT & INDUSTRIAL PHARMACY 423-430 (1986)
	A37	Arkinstall, W. et al., <i>Efficacy of controlled-release codeine in chronic non-malignant pain: a randomized, placebo-controlled clinical trial</i> , 62 PAIN 169-178 (1995)
	A38	Balant, L.P. and Gex-Fabry, M., ORAL CONTROLLED RELEASE PRODUCTS: THERAPEUTIC AND BIOPHARMACEUTIC ASSESSMENT, Ch II. <i>Controlled Release Products - Pharmacokinetic Aspects</i> , Gundert-Remy, U. and Möller, H. eds., Wissenschaftliche Verlagsgesellschaft mBH, Stuttgart at 21-37 (1990).
	A39	Bannerje, P.S. and Robinson, J.R., <i>Novel Drug Delivery Systems: An Overview of Their Impact on Clinical Pharmacokinetic Studies</i> , 20 (1) CLINICAL PHARMACOKINETICS 1-14 (1991)
	A40	Beaver, W.T. et al., <i>Analgesic Studies of Codeine and Oxycodone in Patients with Cancer. I. Comparisons of Oral with Intramuscular Codeine and of Oral with Intramuscular Oxycodone</i> , 207 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 92-100 (1978)
	A41	Beaver, W.T. et al., <i>Analgesic Studies of Codeine and Oxycodone in Patients with Cancer. II. Comparisons of Intramuscular Oxycodone with Intramuscular Morphine and Codeine</i> , 207 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 101-108 (1978)
	A42	Beckett, A.H., Rate Control in Drug Therapy, Ch. 17: Once daily rate-controlled drug therapy, Prescott, L.F. and Nimmo, W.S. eds., Churchill Livingstone, Edinburgh at 166-179 (1985)
	A43	Benziger, D.P. et al., <i>A Pharmacokinetic/Pharmacodynamic Study of Controlled Release Oxycodone</i> , 13 (2) J. PAIN & SYMPTOM MANAGEMENT 75-82 (1997)
	A44	Bobs, G. et al., <i>Steady-State Pharmacokinetics of Sustained Release Morphine Tablets (MS Contin) and Morphine Sulfate Solution (MSS)</i> , 6 Proceedings of ASCO 44 Abstract #171 (1987).
	A45	Bourget, P. et al., <i>Study of the bioequivalence of two controlled-release formulations of morphine</i> , 33 (11) INTERNATIONAL J. CLINICAL PHARMACOLOGY & THERAPEUTICS 588-94 (1995)
	A46	Brooks, I.M. et al., <i>Continuous Release Morphine Sulfate (CRMS) Tablets in Cancer Patients (pts) with Chronic Pain</i> , 5 Proceedings of ASCO 251 Abstract #980 (1986).
	A47	Brooks, I.M. et al., <i>Use of Continuous Release Morphine Sulfate (CRMS) in Cancer Patients with Chronic Pain</i> , 6 Proceedings of ASCO 264 Abstract #1037 (1987)
	A48	Brooks, J. et al., <i>Principles of Cancer Pain Management: Use of Long-acting Oral Morphine</i> , 28 (3) J. FAMILY PRACTICE 275-280 (1989)
	A49	Bruera, E. et al., <i>A Randomized, Double-Blind, Double-Dummy, Crossover Trial Comparing the Safety and Efficacy of Oral Sustained-Release Hydromorphone With Immediate-Release Hydromorphone in Patients with Cancer Pain</i> , 14 (5) J. CLINICAL ONCOLOGY 1713-1717 (1996)
	A50	Bruera, E. et al., <i>Randomized, Double-Blind, Cross-Over Trial Comparing Safety and Efficacy of Oral Controlled-Release Oxycodone With Controlled-Release Morphine in Patients With Cancer Pain</i> , 16 (10) J. CLINICAL ONCOLOGY 3222-3229 (1998)
	A51	Chary, S. et al., <i>The Dose-Response Relationship of Controlled Release Codeine (Codeine Contin) in Chronic Cancer Pain</i> , 9(6) J. PAIN & SYMPTOM MANAGEMENT 363-371 (1994).
	A52	Chmielewski, D.H. et al., <i>Comparative Bioavailability of Multiple Doses of Sustained Release Morphine Tablets (Roxanol</i>

		<i>SR q 12h) and Immediate Release Morphine Solution (q 4h), 6 Proceedings of ASCO 275 Abstract #1080 (1987)</i>
	A53	Citron, M.L. et al., <i>Long-Term Administration of Controlled-Release Oxycodone Tablets for the Treatment of Cancer Pain</i> , 16(8) CANCER INVESTIGATION 562-571 (1998).
	A54	Comerford, T., <i>Efficacy of Controlled-Release Oxycodone</i> , Letters to the Editor, 17 (2) J. CLINICAL ONCOLOGY 738 (1999)
	A55	Cowan, D.A. et al., <i>Two Assays for Dihydrocodeine in Plasma and in Urine and Their Use to Determine the Bioavailability of a Controlled-Release Product</i> , 77 (7) J. PHARMACEUTICAL SCIENCES 606-609 (1988)
	A56	Cundiff, D. et al., <i>Evaluation of a Cancer Pain Model for the Testing of Long-Acting Analgesics: The Effect of MS Contin in a Double-Blind, Randomized Crossover Design</i> , 63 (11) CANCER JUNE 1 SUPPLEMENT 2355-2359 (1989)
	A57	Curtis, G.B. et al., <i>Relative Potency of Controlled-Release Oxycodone and Controlled-Release Morphine in Postoperative Pain Model</i> , 55 EUROPEAN J. CLINICAL PHARMACOLOGY 425-429 (1999)
	A58	Deschamps, M. et al., <i>The Evaluation of analgesic effects in cancer patients as exemplified by a Double-Blind, Crossover Study of Immediate-Release versus Controlled-Release Morphine</i> , 7 (7) J. PAIN SYMPTOM MANAGEMENT 384-392 (1992)
	A59	Dhaliwal, H.S. et al., <i>Randomized Evaluation of Controlled-Release Codeine and Placebo in Chronic Cancer Pain</i> , 10 (8) J. PAIN & SYMPTOM MANAGEMENT 612-623 (1995)
	A60	DiPersio, D.M. and Moses, S.S., <i>Predicting plasma procainamide concentrations resulting from a sustained release preparation</i> , 4 CLINICAL PHARMACY 186-191 (1985)
	A61	Esterhail, J.L. et al., <i>Post operative analgesic efficacy of controlled release morphine</i> , Abstract, PAIN (SUPPL. 4) S230 (1987)
	A62	Finn, J.W. et al., <i>Crossover Study of Sustained Release Morphine Sulfate (Roxanol SR) in Advanced Cancer</i> , 6 Proceedings of ASCO 44 Abstract #1027 (1987).
	A63	Finn, J.W., <i>Placebo-Blinded Study of Morphine Sulfate Sustained-Release Tablets and Immediate-Release Morphine Sulfate Solution in Outpatients With Chronic Pain Due to Advanced Cancer</i> , 11 (5) CLINICAL ONCOLOGY 967-972 (1993)
	A64	Fitzmartin, R.D. and Reder, R.F., <i>Stigma associated with opioid therapy for pain, results of a health care provider survey</i> , AMERICAN PAIN SOCIETY, 14 <sup>TH</sup> annual Scientific Meeting, A144 abstract #95877, Nov. 9-12 (1995)
	A65	Foley K.M., <i>The Treatment of Cancer Pain</i> , 313 NEW ENGLAND J. MEDICINE 84-95 (1985)
	A66	Gibaldi, M. and Perrier, D., PHARMACOKINETICS, 2 <sup>nd</sup> Ed., Rev. & Exp., Marcel Dekker, Inc., New York at 456-457; 353-357 (1982)
	A67	Gibaldi, M. and Perrier, D., PHARMACOKINETICS, Ch. 4: Absorption Kinetics and Bioavailability, 2 <sup>nd</sup> Ed., Rev. & Exp., Marcel Dekker Inc., New York at 145-198 (1985)
	A68	Glare, P.A. and Walsh, D., <i>Oxycodone – a substitute for morphine in cancer pain management?</i> 6 PALLIATIVE MEDICINE 79-80 (1992)
	A69	Gostick, N. et al., <i>A comparison of the efficacy and adverse effects of controlled release dihydrocodeine and immediate release dihydrocodeine in the treatment of pain in osteoarthritis and chronic back pain</i> , The Edinburgh Symposium on Pain Control and Medical Education (R. G. Twycross, ed.), Royal Society of Medicine Services International Congress and Symposium Series No. 149, London, 137-143 (1989)
	A70	Grandy, R. et al., <i>Bioavailability Comparison of Three Controlled-Release Codeine Formulations vs. Conventional Oral Codeine</i> , 3 (3) J. PAIN & SYMPTOM MANAGEMENT ABSTRACT S17 #27 (1988)
	A71	Grass, G.M. and Robinson, J.R., MODERN PHARMACEUTICS, Ch. 16: Sustained and Controlled-Release Drug Delivery Systems, 2 <sup>nd</sup> Ed., Marcel Dekker, Inc., New York at 635-671 (1989)
	A72	Hagen, N.A. and Babul, N., <i>Comparative clinical efficacy and safety of a novel controlled-release oxycodone formulation and controlled-release hydromorphone in the treatment of cancer pain</i> , 79 (7) CANCER 1428-37 (1997)
	A73	Hale, M.E. et al., <i>Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain</i> , 15 CLINICAL J. PAIN 179-183 (1999)
	A74	Hanks, G.W., <i>Controlled-Release Morphine (MST Contin) In Advanced Cancer The European Experience</i> , 63 (11)

		CANCER JUNE 1 SUPPLEMENT 2378-2382 (1989)
	A75	Hays, H. et al., <i>Comparative Clinical Efficacy and Safety of Immediate Release and Controlled Release Hydromorphone for Chronic Severe Cancer Pain</i> , 74 (6) CANCER 1808-1816 (1994)
	A76	Heinrich-Nols, J. et al., <i>Bioequivalence study of two morphine extended release formulations after multiple dosing in healthy volunteers</i> , 37 (3) INTERNATIONAL J. CLINICAL PHARMACOLOGY & THERAPEUTICS 153-158 (1999)
	A77	Heiskanen, T. and Kalso, E., <i>Controlled-Release Oxycodone and Morphine in Cancer Related Pain</i> , 73 PAIN 37-45 (1997).
	A78	Heiskanen, T.E. et al., Morphine or Oxycodone in Cancer Pain?, 39 (8) ACTA ONCOLOGICA 941-947 (2000)
	A79	Hood, G.M. et al., Dose and Effectiveness of Oral Oxycodone Following PCA Morphine For Post-Operative Analgesia, Abstracts 7 <sup>th</sup> World Congress on Pain, 390, Abstract 1028, Poster # 14 (1993)
	A80	Houde, R.W. et al., ANALGETICS, Ch. III: Clinical Measurement of Pain, deStevens, G. ed., Academic Press, New York at 75-122 (1965)
	A81	Houde, R.W., <i>The Use and Misuse of Narcotics in the Treatment of Chronic Pain</i> , 4 ADVANCES IN NEUROLOGY 527-536 (1974)
	A82	Houston, A.C. and Yeang, Y., <i>The Influence of food on the Pharmacokinetics of Morphine from Two controlled Release Preparations</i> , 2 BRITISH J. CLINICAL RESEARCH 201-209 (1991)
	A83	Hunt, T.L. and Kaiko, R.F., <i>Comparison of the Phramacokinetic Profiles of Two Oral Controlled-Release Morphine Formulations in Healthy Young Adults</i> , 13 (4) CLINICAL THERAPEUTICS 482-488 (1991)
	A84	Jamison, R.N. and Ferrante, F.M., Survey of Opioid Use in Chronic Nonmalignant Pain Patients, 11 <sup>th</sup> ANNUAL SCIENTIFIC MEETING, AMERICAN PAIN SOCIETY, Oct. 22, Abstract #92467 (1992)
	A85	Kaiko, R.F. et al., <i>Basics of Opioid Analgesic Pharmacodynamics</i> , 1 (2) J. PAIN & SYMPTOM MANAGEMENT 103-105 (1986)
	A86	Kaiko, R. et al., <i>Pharmacokinetic Characterization of Controlled-Release Oral Codeine for Chronic Cancer Pain</i> , 5 Proceedings of ASCO 255 #996 (1986)
	A87	Kaiko, R.F. et al., <i>Bioequivalency of controlled-release 60 mg morphine vs. two MS Contin 30 mg tablets</i> , ONCOLOGY NURSING FORUM SUPPL MAR-APR 118, ABSTRACT #148P (1987)
	A88	Kaiko, R.F. et al., <i>Bioequivalency of Controlled-Release 100 mg Morphine vs. Three Ms Contin 30 mg Tablets</i> , 6 Proceedings of ASCO 271 Abstract 1066 (1987)
	A89	Kaiko, R.F. et al., <i>The United States Experience With Oral Controlled-Release Morphine (MS Contin Tablets): Parts I and II. Review of Nine Dose Titration Studies and Clinical Pharmacology of 15mg, 30-mg, 60-mg, and 100-mg Tablet Strengths in Normal Subjects</i> , 63 (11) CANCER JUNE 1 SUPPLEMENT 2348-2354 (1989)
	A90	Kaiko, R.F. et al., <i>Controlled-Release Morphine Bioavailability (MS Contin® Tablets) in the Presence and Absence of Food</i> , 6 (4) HOSPICE J. 17-30 (1990)
	A91	Kaiko, R. et al., <i>A single-dose study of the effect of food ingestion and timing of dose administration on the pharmacokinetic profile of 30-mg sustained-release morphine sulfate tablets</i> , 47 (5) CURRENT THERAPEUTIC RESEARCH 869-878 (1990)
	A92	Kaiko, R.F. et al., <i>Controlled-Release Oral Morphine (MS Contin Tablets, MSC) in Postoperative Pain</i> , 183 (6) EUROPEAN J. PHARMACOLOGY 1437-1438 (1990)
	A93	Kaiko, R.F., <i>Controlled-Release Oral morphine for Cancer-Related Pain: The European and North American Experiences</i> , ADVANCES IN PAIN RESEARCH AND THERAPY, vol. 16 K.M. Foley, ed., Raven Press, Ltd., New York at 171-189 (1990)
	A94	Kaiko, R.F., <i>Relationship between opioid disposition and their pharmacological effects – an overview</i> , 67 (SUPPL. 2) POSTGRADUATE MEDICAL J. S44-S49 (1991)
	A95	Kaiko, R.F. et al., <i>The Bioavailability of Morphine in Controlled-Release 30 mg Tablets per Rectum Compared With Immediate-Release 30-mg Rectal Suppositories and Controlled-Release 30-mg Oral Tablets</i> , 12 (2) PHARMACOTHERAPY 107-113 (1992)

	A96	Kaiko, R.F. et al., <i>A Bioequivalence Study of Oral Controlled-Release Morphine Using Naltrexone Blockade</i> , 35 J. CLINICAL PHARMACOLOGY 499-504 (1995)
	A97	Kaiko, R. et al., <i>Analgesic Onset And Potency of Oral Controlled-Release (CR) Oxycodone And CR Morphine</i> , CLINICAL PHARMACOLOGY & THERAPEUTICS, Abstract 130 #PI-4 (1996)
	A98	Kaiko, R. et al., <i>Steady-state Bioavailability Evaluation of Controlled Release Oral Codeine</i> , FASEB J. ABSTRACT A1558 #7333 May 1 – May 5 Meeting of the Federation of American Societies for Experimental Biology (72 <sup>nd</sup> Annual Meeting, Las Vegas NV) (1998)
	A99	Kalso, E., Hallucinations during morphine but not during oxycodone treatment, 2 (8616) The Lancet 912 (1988)
	A100	Kalso, E. and Vainio, A., <i>Morphine and oxycodone hydrochloride in the management of cancer pain</i> , 47 (5) CLINICAL PHARMACOLOGY & THERAPEUTICS 639-646 (1990)
	A101	Kalso, E. et al., <i>Morphine and Oxycodone in the Management of Cancer Pain: Plasma Levels Determined by Chemical and Radioreceptor Assays</i> , 67 PHARMACOLOGY & TOXICOLOGY 322-328 (1990)
	A102	Kalso, E. et al., <i>Intravenous morphine and oxycodone for pain after abdominal surgery</i> , 35 ACTA ANAESTHESIOLOGICA SCANDINAVICA 642-646 (1991)
	A103	Kaplan, R. et al., <i>Comparison of Controlled-Release and Immediate Release Oxycodone Tablets in Patients with Cancer Pain</i> , 16 (10) J. CLINICAL ONCOLOGY 3230-3237 (1998)
	A104	Khan, M. Zahirul I., <i>Dissolution testing for sustained or controlled release oral dosage forms and correlation with in vivo data: challenges and opportunities</i> , 140 INTERNATIONAL J. OF PHARMACEUTICS 131-143 (1996)
	A105	Khojasteh, A. et al., <i>Safety and Efficacy of Slow-Release Morphine Sulfate Tablets in Cancer Pain Therapy</i> , 5 Proceedings of ASCO 256 Abstract #1000 (1986).
	A106	Krant, M. et al., <i>Cancer Pain Management with Controlled-Release Oral Morphine</i> , 5 Proceedings of ASCO 251 Abstract #981 (1986).
	A107	Lapin, J. et al., <i>Cancer pain management with a controlled-release oral morphine preparation</i> , 4 (3) J. PAIN & SYMPTOM MANAGEMENT 146-151 (1989)
	A108	Lazarus, J. & Cooper, J., <i>Absorption, Testing, and Clinical Evaluation of Oral Prolonged-Action Drugs</i> , 50 (9) J. PHARMACEUTICAL SCIENCES 715-732 (1961)
	A109	Leeson, L.J. et al., <i>The In Vitro Development of Extended-Release Solid Oral Dosage Forms</i> , 13 (5) J. PHARMACOKINETICS & BIOPHARMACEUTICS 493-514 (1985)
	A110	Lehmann, K., <i>Acrylic Latices from Redispersable Powders for Peroral and Transdermal Drug Formulations</i> , 12 (3) DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY 265-287 (1986)
	A111	Leow, K.P. et al., <i>Comparative Oxycodone Pharmacokinetics in Humans After Intravenous, Oral, and Rectal Administration</i> , 14 (6) THERAPEUTIC DRUG MONITORING 479-484 (1992)
	A112	Leow, K.P. et al., <i>Single-Dose and Steady-State Pharmacokinetics and Pharmacodynamics of Oxycodone in Patients With Cancer</i> , 52 CLINICAL PHARMACOLOGY & THERAPEUTICS 487-495 (1992)
	A113	Leslie, S.T. et al., <i>Letters to the Editors: Controlled Release Morphine Sulphate Tablets – A Study in Normal Volunteers</i> , 9 BRITISH J. CLINICAL PHARMACOLOGY 531-534 (1980)
	A114	Leslie, S.T., <i>Continus Controlled Release Preparations</i> , Symposium Supplement 10 BRITISH J. CLINICAL PHARMACOLOGY 5-8 (1981)
	A115	Lloyd, R.S. et al., <i>The efficacy and tolerability of controlled-release dihydrocodeine tablets and combination dextropropoxyphene/paracetamol tablets in patients with severe osteoarthritis of the hips</i> , 13 (1) CURRENT MEDICAL RESEARCH OPINIONS 37-48 (1992)
	A116	LoRusso, P. et al., <i>Comparison of Controlled-release oxycodone (OxyContin™) tablets to controlled-release morphine (MS Contin®) in patients with cancer pain</i> , American Pain Society, 15 <sup>th</sup> Annual Scientific Meeting, Abstract #675 (1996)
	A117	LoRusso, P. et al., <i>The Effects of Oral Controlled-Release Morphine and Oxycodone on Cancer-Related Neuropathic Pain</i> , American Pain Society: 17 <sup>th</sup> Annual Scientific Meeting, Poster Abstracts 130 #724 (1998)

	A118	MacDonald, N. et al., <i>A Double-Blind, Cross-Over Comparison Between Slow-Release Morphine (SRM) and Short-Acting Morphine (SAM) in the Treatment of Cancer Pain</i> , 6 Proceedings of ASCO 44 Abstract #1054 (1987)
	A119	Mandema, J.W. et al., <i>Pharmacokinetic Model For A New Oral Controlled Release Formulation Of Oxycodone</i> , 81 (3A) ANESTHESIOLOGY A383 (1994)
	A120	Mucci-LoRusso, P. et al, <i>Controlled-release oxycodone compared with controlled-release morphine in the treatment of cancer pain: a randomized, double-blind, parallel-group study</i> , 2 EUROPEAN J. PAIN 239-249 (1998)
	A121	Paul, D. et al., <i>Pharmacological Characterization of Morphine-6-Beta-Glucuronide, a very potent morphine metabolite</i> , 251 (2) J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 477-483 (1989)
	A122	Physician's Desk Reference, OxyContin, 56 Ed. at 2912-2916, (2002)
	A123	Portenoy, R.K. et al., <i>Oral Controlled-Release Morphine Sulfate, Analgesic Efficacy and Side Effects of a 100-mg Tablet in Cancer Pain Patients</i> , 63 CANCER JUNE 1 SUPPLEMENT 2284-2288 (1989)
	A124	Portenoy, R.K. and Coyle, N., <i>Controversies In The Long-Term Management Of Analgesic Therapy In Patients With Advanced Cancer</i> , 5 (5) J. PAIN & SYMPTOM MANAGEMENT 307-319 (1990)
	A125	Portenoy, R.K. et al., <i>The Metabolite Morphine 6-glucuronide Contributes to the Analgesia Produced by Morphine Infusion in Patients with Pain and Normal Renal Function</i> , 51 (4) CLINICAL PHARMACOLOGY & THERAPEUTICS 422-431 (1992)
	A126	Poyhia, R. et al., <i>The Pharmacokinetics of oxycodone after intravenous injection in adults</i> , 32 BRITISH J. CLINICAL PHARMACOLOGY 516-518 (1991)
	A127	Poyhia, R. et al., <i>The pharmacokinetics and metabolism of oxycodone after intramuscular and oral administration to healthy subjects</i> , 33 (6) BRITISH J. CLINICAL PHARMACOLOGY 617-621 (1992)
	A128	Poyhia, R. et al., <i>A Review of Oxycodone's Clinical Pharmacokinetics and Pharmacodynamics</i> , 8 (2) J. PAIN & SYMPTOM MANAGEMENT 63-67 (1993)
	A129	Reder, R.F. and Fitzmartin, R.D., <i>Physician Survey of Attitudes About Controlled-Release Oxycodone (OXYCR)</i> , AMERICAN PAIN SOCIETY, 14 <sup>th</sup> Annual Scientific Meeting A144 Abstract #95878 Nov. 9-12 (1995)
	A130	Reder, R. et al., Ease of Titration to Stable Pain Control in Chronic Pain Patients with Controlled-Release Oral Oxycodone (OxyContin™) Tablets, Abstracts, 8 <sup>th</sup> World Congress on Pain, Vancouver, Canada, August 17-22, 53 Abstract #171, (1996)
	A131	Reder, R.F. et al., <i>Steady-State Bioavailability of Controlled-Release Oxycodone in Normal Subjects</i> , 18 (1) CLINICAL THERAPEUTICS 95-105 (1996)
	A132	Renzi, N.L. and Tam, J.N., <i>Quantitative GLC Determination of Oxycodone in Human Plasma</i> , 68 (1) J. PHARMACEUTICAL SCIENCES 43-45 (1979)
	A133	Riegelman, S. and Collier, P., <i>The application of statistical moment theory to the evaluation of in vivo dissolution time and absorption time</i> , 8 (5) J. PHARMACOKINETICS & BIOPHARMACEUTICS 509-534 (1980)
	A134	Robinson, J.R. and Eriksen, S.P., <i>Theoretical formulation of sustained-release dosage forms</i> , 55 (11) J. PHARMACEUTICAL SCIENCES 1254-1263 (1966)
	A135	Robinson, J.R. and Eriksen, S.P., <i>Theoretical approach to sustained-release multiple-dose therapy: noncumulative attainment of desired blood level</i> , 59 (12) J. PHARMACEUTICAL SCIENCES 1796-1800 (1970)
	A136	Rodda, B.E., <i>Sustained Release Preparations: Estimation of Plasma Concentration in the One Compartment Open Model when Release is both Immediate and Zero Order</i> , 194 ARCHIVES INTERNATIONALES DE PHARMACODYNAMIC ET DE THERAPIE 290-296 (1971)
	A137	Rogers, A.G., <i>The Underutilization of Oxycodone</i> , 6 (7) J. PAIN & SYMPTOM MANAGEMENT 452 (1991)
	A138	Salzman, R.F. et al., <i>Can a Controlled-Release Oral Dose Form of Oxycodone Be Used as Readily as an Immediate-Release Form For the Purpose of Titrating to Stable Pain Control?</i> , 18 (4) J. PAIN & SYMPTOM MANAGEMENT 271-279 (1999)
	A139	Savarese, J.J. et al., <i>Steady-State Pharmacokinetics of Controlled Release Oral Morphine Sulphate in Healthy Subjects</i> , 11 CLINICAL PHARMACOKINETICS 505-510 (1986)
	A140	Savarese, J. et al., <i>Controlled-Release Oral Morphine Sulfate (MS Contin®), A Twelve Hour Analgesic Confirmed by Rescue</i>

		<i>Factor Design</i> , 6 Proceedings of ASCO 264 Abstract #1038 (1987).
	A141	Sawe, J. et al., <i>Morphine kinetics in cancer patients</i> , 30 (5) CLINICAL PHARMACOLOGY & THERAPEUTICS 629-635 (1981)
	A142	Steinbach, D. et al., <i>Evaluation of Pharmaceutical Availability from the Calculation of Drug Levels and Release Profiles</i> , 4 INTERNATIONAL J. OF PHARMACEUTICS 327-335 (1980)
	A143	Stelmach, H. et al., <i>Release of a Drug from a Dosage Form</i> , 54 (10) J. PHARMACEUTICAL SCIENCES 1453-1458 (1965)
	A144	Sun, H. and Moses, S.S. Chow, <i>A Method of Determining the In Vivo Drug Release Rate Constant of Sustained-Release Preparation</i> , 23 (4) DRUG METABOLISM AND DISPOSITION 449-454 (1995)
	A145	Sunshine, A. et al., <i>Analgesic Effects of Oral Oxycodone and Codeine in the Treatment of Patients with Postoperative, Postfracture, or Somatic Pain</i> , 8 ADVANCES PAIN RESEARCH THERAPY, Foley, K.M. and Inturrisi, C.E. eds., Raven Press, New York 225-235 (1986)
	A146	Sunshine, A. et al., <i>Analgesic Efficacy of Controlled-Release Oxycodone vs. Immediate-Release Oxycodone Alone and in Combination with Acetaminophen in Postoperative Pain: A Preliminary Study</i> , Problems of Drug Dependence, 1992: Proceeding of the 54 <sup>th</sup> Annual Scientific Meeting, U.S. Department of Health and Human Services, 329 (1992)
	A147	Sunshine, A. et al., <i>Controlled-Release Oxycodone vs. Immediate Release Oxycodone Alone and in Combination with Acetaminophen in the Treatment of Postoperative Pain</i> , 11 <sup>th</sup> Annual Scientific Meeting, American Pain Society, Oct. 22, Abstract #92466 (1992)
	A148	Sunshine, A. et al., <i>Onset And Duration Of Analgesia For Controlled Release Vs. Immediate Release Oxycodone Alone And In Combination With Acetaminophen In Postoperative Pain</i> , 57 (2) CLINICAL PHARMACOLOGY & THERAPEUTICS 137 Abstract #PI-7 (1995)
	A149	Sunshine, A. et al., <i>Analgesic Efficacy of Controlled-Release Oxycodone in Postoperative Pain</i> , 36 (7) J. CLINICAL PHARMACOLOGY 595-603 (1996)
	A150	Thirlwell, M.P. et al., <i>Pharmacokinetics and Clinical Efficacy of Oral Morphine Solution and Controlled-Release Morphine Tablets in Cancer Patients</i> , 63 (11) CANCER JUNE 1 SUPPLEMENT 2275-2283 (1989)
	A151	Wagner, J., <i>Biopharmaceutics: 23: Rate of Dissolution In Vitro and In Vivo: Part VIII. Examples of Quantitative Correlations of in Vivo with in Vitro Data</i> , 4 DRUG INTELLIGENCE AND CLINICAL PHARMACY 232-239 (1970)
	A152	Wagner, J., BIOPHARMACEUTICS, Ch. 21: <i>Quantitative Correlations of in Vivo Data with in Vitro Rate of Dissolution Data</i> , 1 <sup>st</sup> ed., Drug Intelligence Publications, Illinois at 140-147 (1971)
	A153	Walsh, T.D. et al., <i>Disposition of Oral Morphine in Advanced Cancer</i> , 6 Proceedings of ASCO 270 Abstract #1063 (1987).
	A154	Welling, P.G. and Dobrinska, M.R., SUSTAINED AND CONTROLLED RELEASE DRUG DELIVERY SYSTEMS, Ch. 9: <i>Multiple Dosing of Sustained Release Systems</i> , J.R. Robinson, ed., Marcel Dekker, Inc., New York at 631-716 (1978)
	A155	Welling, P.G., PHARMACEUTICAL BIOEQUIVALENCE - Ch. 8 - <i>In Vitro Methods to Determine Bioavailability: In Vitro-In Vivo Correlations</i> , Marcel Dekker, Inc., New York at 223-232 (1991)
	A156	Wiegand, R.G. and Taylor, J.D., <i>Kinetics of Plasma Drug Levels after Sustained Release Dosage</i> , 3 BIOCHEMICAL PHARMACOLOGY 256-263 (1960)
	A157	Wilson, A.B and Draffan, G.H., RATE CONTROL IN DRUG THERAPY, Ch. 4: Implications of Toxicology, Prescott, L.F. and Nimmo, W.S. eds., Churchill Livingstone, Edinburgh at 30-37 (1985)
	A158	Wotherspoon, H.A. et al., <i>Analgesic efficacy of controlled-release dihydrocodeine: A comparison of 60, 90 and 120 mg tablets in cold-induced pain</i> , 46 ANAESTHESIA 915-917 (1991)
	A159	The Merck Index, 11 <sup>th</sup> ed., Budavari, S. ed., at pages 384-385, 500, 762, 988, and 1100 (1989)
	A160	Federal District Court Decision, <i>Purdue Pharma, L.P., v. Boehringer Ingelheim GmbH</i> , 98 F. Supp. 2d. 362; 2000, U.S. Dist., S.D.N.Y., U.S.P.Q. 2D 1168, Judge Sidney Stein decided May 16, 2000.
	A161	Federal Court of Appeals Decision, <i>Purdue Pharma, L.P., v. Boehringer Ingelheim GmbH</i> , Docket No. 00-1398, Judge Sidney Stein, decided February 1, 2001.
	A162	Purdue's Proposed Findings Of Fact And Conclusions Of Law After Trial in <i>Purdue Pharma L.P., The Purdue Frederick</i>

		<i>Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs and Counterclaim Defendants) v. Endo Pharmaceuticals, Inc. (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings, Inc. (Defendant) v. EuroCeltique S.A.(Counterclaim Defendant)</i> Civil Action Nos. 00-Civ. 8029 (SHS); 01-Civ. 2109 (SHS); Civil Action Nos. 01-Civ. 8117 (SHS)
	A163	Endo's Post-Trial Proposed Conclusions Of Law in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs and Counterclaim Defendants) v. Endo Pharmaceuticals, Inc. (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings, Inc. (Defendant) v. EuroCeltique S.A.(Counterclaim Defendant)</i> Civil Action Nos. 00-Civ. 8029 (SHS); 01-Civ. 2109 (SHS); Civil Action Nos. 01-Civ. 8117 (SHS)
	A164	Endo's Post-Trial Proposed Findings of Fact in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs and Counterclaim Defendants) v. Endo Pharmaceuticals, Inc. (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings, Inc. (Defendant) v. EuroCeltique S.A.(Counterclaim Defendant)</i> Civil Action Nos. 00-Civ. 8029 (SHS); 01-Civ. 2109 (SHS); Civil Action Nos. 01-Civ. 8117 (SHS)
	A165	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Impax Laboratories, Inc.</i> , Civil Action No. 02 CV 2803 (SHS)
	A166	Impax's Answer and Counterclaims in Civil Action No. 02 CV 2803 (SHS)
	A167	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Impax Laboratories, Inc.</i> , Civil Action No. 02 CV 7569 (SHS)
	A168	Impax's Answer and Counterclaims in Civil Action No. 02 CV 7569 (SHS)
	A169	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Impax Laboratories, Inc.</i> , Civil Action No. 02 CV 8036 (SHS)
	A170	Impax's Answer and Counterclaims in Civil Action No. 02 CV 8036 (SHS)
	A171	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Teva Pharmaceuticals USA, Inc.</i> , Civil Action No. 01 CV 8507 (SHS)
	A172	Teva's Answer and Counterclaims in Civil Action No. 01 CV 8507 (SHS)
	A173	Purdue's Reply to Answer and Counterclaims in Civil Action No. 01 CV 8507 (SHS)
	A174	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Teva Pharmaceuticals USA, Inc.</i> , Civil Action No. 01 CV 11212 (SHS)
	A175	Teva's Answer in Civil Action No. 01 CV 11212 (SHS)
	A176	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Teva Pharmaceuticals USA, Inc.</i> , Civil Action No. 03 CV 2312 (SHS)
	A177	Teva's Answer and Counterclaims in Civil Action No. 03 CV 2312 (SHS)
	A178	Purdue's Reply to Answer and Counterclaims in Civil Action No. 03 CV 2312 (SHS)
	A179	Prosecution File History, U.S. Patent No. 4,861,598, filed July 18, 1986

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<b>LIST OF REFERENCES CITED BY APPLICANT</b>  (Use several sheets if necessary)				ATTY DOCKET NO.	APPLICATION NO	
				200.93311 CON8 To be Assigned		
				APPLICANT	Benjamin OSHLACK, et al.	
				FILING DATE	GROUP	
				Herewith		

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	B01	2,738,303	03/13/56	Blythe	167	82	
	B02	3,634,584	01/11/72	Poole	424	21	
	B03	3,845,770	11/05/74	Theeuwes et al.	128	260	
	B04	3,870,790	03/11/75	Lowey et al.	424	19	
	B05	3,916,899	11/04/75	Theeuwes et al.	128	260	
	B06	4,063,064	12/13/77	Saunders et al.	219	121	
	B07	4,088,864	05/09/78	Theeuwes et al.	219	121 LM	
	B08	4,132,753	01/02/79	Blichare et al.	264	75	
	B09	4,259,314	03/31/81	Lowey	424	19	
	B10	4,351,825	09/28/82	Sothmann et al.	424	19	
	B11	4,369,172	01/18/83	Schor et al.	424	19	
	B12	4,377,568	03/22/83	Chopra	424	31	
	B13	4,385,078	05/24/83	Onda et al.	427	3	
	B14	4,389,393	06/21/83	Schor et al.	424	19	
	B15	4,421,736	12/20/83	Walters	424	19	
	B16	4,438,091	03/24/92	Gruber et al.	424	21	
	B17	4,464,378	08/07/84	Hussain	424	260	
	B18	4,483,847	11/20/84	Augart	424	22	
	B19	4,520,172	05/28/85	Lehmann et al.	525	369	
	B20	4,548,990	10/22/85	Mueller et al.	525	123	
	B21	4,557,925	12/10/85	Lindahl et al.	424	19	
	B22	4,600,645	07/15/86	Ghebre-Sellassie et al.	428	403	
	B23	4,609,542	09/02/86	Pano, et al.	424	19	
	B24	4,728,513	03/01/88	Ventouras	424	461	
	B25	4,797,410	01/10/89	El-Fakahany	514	356	
	B26	4,806,337	02/21/89	Snipes et al.	71	65	
	B27	4,844,907	07/04/89	Elger et al.	424	465	
	B28	4,894,234	01/16/90	Sharma et al.	424	440	
	B29	4,935,246	06/19/90	Ahrens	424	490	
	B30	4,983,730	01/08/91	Domeshek et al.	536	69	
	B31	5,007,790	04/16/91	Shell	424	451	
	B32	5,019,397	05/28/91	Wong et al.	424	473	
	B33	5,023,089	06/11/91	Sakamoto et al.	424	502	
	B34	5,024,842	06/18/91	Edgren et al.	424	473	
	B35	5,026,560	06/25/91	Makino et al.	424	494	
	B36	5,030,400	07/09/91	Danielsen et al.	264	101	

	B37	5,068,110	11/26/91	Fawzi et al.	424	461	
	B38	5,071,646	12/10/91	Malkowska et al.	424	497	
	B39	5,098,718	03/24/92	Ardaillon et al.	426	2	
	B40	5,122,384	06/16/92	Paradissis et al.	424	451	
	B41	5,126,145	06/30/92	Evenstad et al.	424	465	
	B42	5,132,142	07/21/92	Jones et al.	427	196	
	B43	5,133,974	07/28/92	Paradissis et al.	424	480	
	B44	5,167,964	12/01/92	Muhammed et al.	424	482	
	B45	5,169,645	12/08/92	Shukla et al.	424	499	
	B46	5,178,868	01/12/93	Malmqvist et al.	424	490	
	B47	5,196,203	03/23/93	Boehm	424	469	
	B48	5,202,128	04/13/93	Morella et al.	424	469	
	B49	5,206,030	04/27/93	Wheatley et al.	424	490	
	B50	5,219,575	06/15/93	Von Bommel et al.	424	490	
	B51	5,248,516	09/28/93	Wheatley et al.	427	3	
	B52	5,258,436	11/02/93	Wheatley et al.	524	388	
	B53	5,283,065	02/01/94	Doyon et al.	424	467	
	B54	5,292,461	03/08/94	Juch et al.	264	37	
	B55	5,321,012	06/14/94	Mayer et al.	514	25	
	B56	5,330,766	07/19/94	Morella et al.	424	490	
	B57	5,378,474	01/03/95	Morella et al.	424	469	
	B58	5,384,130	01/04/95	Kamada	424	461	
	B59	5,411,745	05/02/95	Oshlack, et al.	424	456	
	B60	5,456,923	10/10/95	Nakamichi et al.	424	489	
	B61	5,460,826	10/24/95	Merrill et al.	424	470	
	B62	5,472,712	12/05/95	Oshlack et al.	424	480	
	B63	5,478,577	12/26/95	Sackler et al.	424	489	
	B64	5,500,227	03/19/96	Oshlack et al.	424	476	
	B65	5,502,058	03/26/96	Mayer et al.	514	289	
	B66	5,520,931	05/28/96	Persson et al.	424	473	
	B67	5,580,578	12/03/96	Oshlack et al.	424	468	
	B68	5,593,695	01/14/97	Merril, et al.	424	480	
	B69	5,601,842	02/11/97	Bartholomaeus	424	464	
	B70	5,614,218	03/25/97	Olsson	424	456	
	B71	5,629,011	05/13/97	Illum	424	434	
	B72	5,637,320	06/10/97	Bourke et al.	424	489	
	B73	5,667,805	09/16/97	Merrill et al.	424	473	
	B74	5,670,172	09/23/97	Buxton et al.	424	495	
	B75	5,672,360	09/30/97	Sackler et al.	424	490	
	B76	5,681,585	10/28/97	Oshlack et al.	424	494	
	B77	5,843,480	12/01/98	Miller et al.	424	484	
	B78	5,849,240	12/15/98	Miller et al.	264	460	
	B79	5,879,705	03/09/99	Heafield et al.	424	464	
	B80	5,891,471	04/06/99	Miller et al.	424	468	
	B81	5,958,459	09/28/99	Chasin et al.	424	490	

	B82	5,965,163	10/12/99	Miller et al.	424	468	
	B83	6,143,322	11/07/00	Sackler et al.	424	459	

### FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B84	0097523 (B1)	06/21/83	EPO	A61K	9/26	<input type="checkbox"/>	<input type="checkbox"/>
	B85	0097523 (A2)	06/21/83	EPO	A61K	9/26	<input type="checkbox"/>	<input type="checkbox"/>
	B86	0097523 (A3)	06/21/83	EPO	A61K	9/26	<input type="checkbox"/>	<input type="checkbox"/>
	B87	0108218 (A2)	05/16/84	EPO	A61K	9/22	<input type="checkbox"/>	<input type="checkbox"/>
	B88	0147780 (A2)	07/10/85	EPO	A61K	9/32	<input type="checkbox"/>	<input type="checkbox"/>
	B89	0235986 (A1)	09/09/87	EPO	A61K	9/16	<input type="checkbox"/>	<input type="checkbox"/>
	B90	0235986 (B1)	02/12/87	EPO	A61K	9/16	<input type="checkbox"/>	<input type="checkbox"/>
	B91	0235986 (B2)	02/12/87	EPO	A61K	9/16	<input type="checkbox"/>	<input type="checkbox"/>
	B92	0253104 (A1)	01/20/88	EPO	A61K	9/00	<input type="checkbox"/>	<input type="checkbox"/>
	B93	0253104 (B1)	05/22/87	EPO	A61K	9/00	<input type="checkbox"/>	<input type="checkbox"/>
	B94	0267702 (A3)	05/18/88	EPO	A61K	914	<input type="checkbox"/>	<input type="checkbox"/>
	B95	0271193 (A2)	10/22/87	EPO	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B96	0271193 (A3)	10/22/87	EPO	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B97	0271193 (B1)	06/88	EPO	A61K	31/185	<input type="checkbox"/>	<input type="checkbox"/>
	B98	0327295 (A2)	08/09/89	EPO	A61K	9/52	<input type="checkbox"/>	<input type="checkbox"/>
	B99	0361680 (B1)	07/13/94	EPO	A61K	9/46	<input type="checkbox"/>	<input type="checkbox"/>
	B100	0361910 (A1)	04/04/90	EPO	A61K	9/16	<input type="checkbox"/>	<input type="checkbox"/>
	B101	0377517 (A2)	07/11/90	EPO	A61K	31/52	<input type="checkbox"/>	<input type="checkbox"/>
	B102	0377518 (A2)	01/05/90	EPO	A61K	9/52	<input type="checkbox"/>	<input type="checkbox"/>
	B103	0377518 (A3)	01/05/90	EPO	A61K	9/52	<input type="checkbox"/>	<input type="checkbox"/>
	B104	0377518 (B1)	07/11/90	EPO	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B105	0388954 (A2)	03/22/90	EPO	A61K	9/14	<input type="checkbox"/>	<input type="checkbox"/>
	B106	0388954 (A3)	03/22/90	EPO	A61K	9/14	<input type="checkbox"/>	<input type="checkbox"/>
	B107	0388954 (B1)	03/22/90	EPO	A61K	9/14	<input type="checkbox"/>	<input type="checkbox"/>
	B108	0415693 (A1)	03/06/91	EPO	A61K	37/02	<input type="checkbox"/>	<input type="checkbox"/>
	B109	0430287 (B1)	10/12/94	EPO	A61K	9/54	<input type="checkbox"/>	<input type="checkbox"/>
	B110	0452145 (A2)	10/16/91	EPO	A61K	9/14	<input type="checkbox"/>	<input type="checkbox"/>
	B111	0532348 (A2)	03/17/93	EPO	A61K	31/135	<input type="checkbox"/>	<input type="checkbox"/>
	B112	0532348 (A3)	09/11/92	EPO	C07C	291/04	<input type="checkbox"/>	<input type="checkbox"/>
	B113	0532348 (B1)	09/11/92	EPO	C07C	291/04	<input type="checkbox"/>	<input type="checkbox"/>
	B114	0533297 (A1)	03/24/93	EPO	A61K	9/16	<input type="checkbox"/>	<input type="checkbox"/>
	B115	0534628 (A1)	03/21/93	EPO	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B116	0534628 (B1)	04/09/92	EPO	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B117	0535841 (A1)	04/07/93	EPO	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B118	0546676 (A1)	06/16/93	EPO	A61K	31/60	<input type="checkbox"/>	<input type="checkbox"/>
	B119	0548448 (A1)	06/30/93	EPO	A61K	9/50	<input type="checkbox"/>	<input type="checkbox"/>
	B120	0553392 (A1)	08/04/93	EPO	A61K	9/50	<input type="checkbox"/>	<input type="checkbox"/>
	B121	0576643	11/25/92	EPO	A61K	9/22	<input type="checkbox"/>	<input type="checkbox"/>
	B122	0580860 (A1)	02/02/94	EPO	A61K	9/14	<input type="checkbox"/>	<input type="checkbox"/>

	B123	0609961 (A1)	08/10/94	EPO	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B124	0636370 (A1)	02/01/95	EPO	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B125	0636370 (B1)	06/09/94	EPO	A61K	31/35	<input type="checkbox"/>	<input type="checkbox"/>
	B126	0665010 (A1)	08/02/95	EPO	A61K	9/26	<input type="checkbox"/>	<input type="checkbox"/>
	B127	1258246 (A2)	11/20/02	EPO	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B128	80/00659	09/26/79	PCT	A61K	9/32	<input type="checkbox"/>	<input type="checkbox"/>
	B129	92/02209 (A1)	02/20/92	PCT	A61K	9/22	<input type="checkbox"/>	<input type="checkbox"/>
	B130	92/01446	02/06/92	PCT	A61K	9/50	<input type="checkbox"/>	<input type="checkbox"/>
	B131	92/06679	04/30/92	PCT	A61K	9/16	<input type="checkbox"/>	<input type="checkbox"/>
	B132	92/08459	05/29/92	PCT	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B133	93/04675	03/18/93	PCT	A61K	31/16	<input type="checkbox"/>	<input type="checkbox"/>
	B134	93/07859 (A1)	04/29/93	PCT	A61K	9/16	<input type="checkbox"/>	<input type="checkbox"/>
	B135	93/07861	04/29/93	PCT	A61K	9/50	<input type="checkbox"/>	<input type="checkbox"/>
	B136	93/10765	06/93	PCT	A61K	9/22	<input type="checkbox"/>	<input type="checkbox"/>
	B137	93/18753	09/30/93	PCT	A61K	9/16	<input type="checkbox"/>	<input type="checkbox"/>
	B138	94/03160	02/17/94	PCT	A61K	9/32	<input type="checkbox"/>	<input type="checkbox"/>
	B139	94/03161	02/94	PCT	A61L	9/25	<input type="checkbox"/>	<input type="checkbox"/>
	B140	94/05262	03/17/94	PCT	A61K	9/16	<input type="checkbox"/>	<input type="checkbox"/>
	B141	94/22431	10/13/94	PCT	A61K	9/20	<input type="checkbox"/>	<input type="checkbox"/>
	B142	96/00066	01/04/96	PCT	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B143	96/01629	01/25/96	PCT	A61K	31/485	<input type="checkbox"/>	<input type="checkbox"/>
	B144	96/14058	05/27/96	PCT	A61K	9/14	<input type="checkbox"/>	<input type="checkbox"/>
	B145	01/08661 (A2)	07/27/00	PCT	A61K	9/00	<input type="checkbox"/>	<input type="checkbox"/>
	B146	2082573	11/10/92	Canada	A61K	047/38	<input type="checkbox"/>	<input type="checkbox"/>
	B147	2131350 (A1)	01/94	Canada	A61K	031/135	<input type="checkbox"/>	<input type="checkbox"/>
	B148	2053681 (B)	04/04/84	Great Britain	A61K	9/22	<input type="checkbox"/>	<input type="checkbox"/>
	B149	2178313 (A)	02/11/87	Great Britain	A61K	9/14	<input type="checkbox"/>	<input type="checkbox"/>
	B150	2196848	05/11/88	Great Britain	A61K	9/22	<input type="checkbox"/>	<input type="checkbox"/>
	B151	04081086	04/02/92	Japan	A61K	9	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	B152	2170104	07/30/86	United Kingdom	A61K	9/58	<input type="checkbox"/>	<input type="checkbox"/>
	B153	9047732	07/12/90	Australia			<input type="checkbox"/>	<input type="checkbox"/>
	B154	9341654	02/16/95	Australia	A61K	009/36	<input type="checkbox"/>	<input type="checkbox"/>

**OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)**

	B155	Abstract of Japan, XP-002241447, May 12, 1988
	B156	Abstracts from the Twelfth Annual Congress of the Oncology Nursing Society, May 1987
	B157	Advertisement: MS Contin 1986, 1987 The Purdue Frederick Company
	B158	Advertisement: Roxanol SR., 1988 Roxane Labs, Inc.
	B159	Beubler, E., "Medikamentose Schmerztherapie: Kriterien, Möglichkeiten, Risiken," <i>Therapiewoche Österreich</i> , 7, 2 (1992), pages 1-15, English translation.
	B160	Bloomfield, MD, Saul S., et al., "Analgesic efficacy and potency of two oral controlled release morphine preparations", <i>Clin. Pharm &amp; Therapeutics</i> , Vol. 53, No. 4 (1993) pages 469-478
	B161	Flanders, P., et al., "The Control of Drug Release From Conventional Melt Granulation Matrices," <i>Drug Development and Industrial Pharmacy</i> , vol. 13, No. 6, pp. 1001-1022 (1987)
	B162	Gourlay, Geoffrey K., Ph.D., et al., "Influence of a high-fat meal on the absorption of morphine from oral solutions," <i>Clin. Pharmacol. Ther.</i> , October 1989, pages 463-468
	B163	Gourlay, Geoffrey K., Ph.D., Ph.D., "The Reproducibility of Bioavailability of Oral Morphine from Solution Under Fed and Fasted Conditions," <i>Journal of Pain and Symptom Management</i> , Vol. 6., No. 7, October 1991, pages 431-436

	B164	Kaiko, R.F. "The Pre-and Postoperative Use of Controlled-Release Morphine (MS Contin Tablets): A Review of the Published Literature" Medical Department, The Purdue Frederick Company, Royal Society of Medical Services, International Congress, Symposium Services, No. 149, pp. 147-160 (1989)
	B165	Kaiko, R.F. "Clinical Protocol and Role of Controlled Release Morphine in the Surgical Patient" Anesthesiology and Pain Management 1991 pp 193-212
	B166	Lapin, J., et al., "Guidelines for use of Controlled Release Oral Morphine in Cancer pain Management," Cancer Nursing, v 12 (4), pp. 202-8, 1989
	B167	McTaggart, Celia M., et al., "The evaluation of formulation and processing conditions of a melt granulation process," International Journal of Pharmaceutics, Vol. 19, pp. 139-148 (1984)
	B168	Munday, D.L., "Changes in Drug Release Rate 2, Effect of Temperature and Relative Humidity on Polymeric Film Coatings," 5 <sup>th</sup> Cong. Int. Tech. Pharm., 1989, Vol. 2, pp. 55-60.
	B169	Physicians Desk Reference 1994, 48 <sup>th</sup> Edition, pages 1821-1824.
	B170	Schaefer, T., et al., "Melt granulation in a laboratory scale high shear mixer," Drug Development and Industrial Pharmacy, Vol. 16, No. 8, pp. 1249-1277 (1990)
	B171	Slowey, H.F., et al., "Effect of Premedication with Controlled-Release Oral Morphine on Postoperative Pain," Anaesthesia, 1985, Vol. 40, pp. 438-40.
	B172	Sunshine, Abraham et al., "Analgesic oral efficacy of tramadol hydrochloride in postoperative pain," Clin. Pharmacol. Ther., June 1992, pages 740-746.
	B173	Sustained Release Medications, Noyes Data Corp., pages 3,4, 10-15, 96-99, 335-337 (1980).
	B174	Thomsen, L. Juul, "Utilizing melt pelletization technique for the preparation of prolonged release products," Pelletization, (material elaborated by assistant prof. Lars Juul Thomsen, Department of Pharmaceutics, Royal Danish School of Pharmacy for the DIE course "Pelletization Technologh," November 1992, 106 pages plus 3 appendices
	B175	Thomsen, L. Juul, et al., "Prolonged Release Matrix Pellets Prepared by Melt Pelletization I. Process Variables," Drug Development and Industrial Pharmacy, Vol. 19, No. 15, pp. 1867-1887 (1993)
	B176	Thomsen, L. Juul, "Prolonged Release Matrix Pellets Prepared by Melt Pelletization. Part IV: Drug Particles Size, and Binder Composition," Pharmaceutical Technology Europa, pp. 19-24 (October 1994)
	B177	Yokokawa, N., et al., "Relationship between plasma concentration of morphine and analgesic effectiveness," Postgrad Med J, (1991) 67 (Suppl. 2) pages S50-S54

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	